

Attorney Docket No.: J3692(C)  
Serial No.: 10/531,155  
Filed: September 26, 2005  
Confirmation No.: 4686

### REMARKS

Claims 9 and 11 are hereby cancelled without prejudice, with Applicants reserving the right to file a divisional application thereto. Claim 8 has been amended to specify that it is a method for the treatment of dandruff. Claim 10 has been amended to specify that it is a method for the treatment of scalp itch. It is believed that these amendments moot the rejection of claims 8 to 11 under 35 USC §112, and the rejection of claims 9 and 11 under 35 USC §101.

New claim 12 specifies that the composition is formulated as a transparent or opaque emulsion, lotion, cream, past or gel, for treating scalp itch. See, for example, page 1, lines 2 to 8, and the last paragraph at page 26. New claim 13 requires that at least 20% of the conjugated linoleic acid (CLA) is present in specified ionic forms. See, for example, the last paragraph of 7 and the first paragraph of page 8.

In view of the amendment set forth above and the remarks that follow, reconsideration and allowance of the subject claims, as hereby amended, is respectfully requested.

Pursuant to the Office Action of April 3, 2007 claims 1-11 were rejected under 35 U.S.C. 103(a) as unpatentable over Hoppe et al. (US 2003/0180277) in view of Hersh (US 6011067). The Action maintains that:

Hoppe teaches anti-dandruff compositions for scalp. The reference teaches adding conjugated fatty acid, particularly conjugated linoleic acid in the weight amount of 0.0001-5%, to promote the energy metabolism of the hair root... The reference employs bioquinone as the anti-dandruff agent, and does not teach the anti-dandruff agents of the instant claims. Hersh teaches that zinc pyrithione has been used for treatment of dandruff, seborrheic dermatitis, flakes and other skin maladies...It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the composition of Hoppe by substituting bioquinones with or incorporating, zinc

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pyrithione as motivated by Hersh, because both of the components are functionally equivalent anti-dandruff agents well known in the art....,

Pursuant to the subject invention it was found that the combination of a selected antidandruff agent and CLA provide a synergistic benefit in terms of reducing scalp itch associated with dandruff. Applicants carried out testing to assess the effect of CLA used in conjunction with an anti-dandruff shampoo containing zinc pyrithione (1%) and otherwise identical shampoos in which lacked zinc pyrithione. The CLA was incorporated into a separate treatment composition (i.e., a lotion), at a level of 3%; an otherwise identical lotion was made, but without CLA. Thus, the protocol employed the two shampoos and two lotions. The testing involved 4 panellist groups, with 60 panellists per group (each with self-perceived dandruff). According to the protocol: Group 1 was washed their hair with the non-antidandruff shampoo 3 times a week and applied the CLA-containing lotion one hour prior to washing; Group 2 washed their hair with the non-antidandruff shampoo 3 times a week and applied the non-CLA lotion one hour prior to washing; Group 3 washed their hair with the anti-dandruff shampoo 3 times a week and applied the CLA-containing lotion one hour prior to washing; and Group 4 washed their hair 3 times a week and applied the non-CLA lotion one hour prior to washing. After 4 weeks the panellists were instructed not to apply the lotion product for the next five weeks, i.e., shampooing continued as before but without the use of the lotion. Over the course of the test, the panellists were interviewed once a week in order to assess the degree of scalp itching they were experiencing.

Results of the tests are illustrated in Figure 1 of the specification. Group 3 (anti-dandruff shampoo + CLA lotion) experienced the lowest degree of scalp itching of the four groups. Group 1 (non-antidandruff shampoo +CLA lotion) had a **higher degree** of itch than the Group 2 (non-antidandruff shampoo + non-CLA lotion). The comparison of Groups 1 and 2 shows that CLA use can actually increase the degree of scalp itch. Based on the results for Groups 1 and 2, it is surprising that when the

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use of the CLA lotion was combined with the use of the zinc PTO containing antidandruff shampoo, that itching would be reduced. Accordingly, it is respectfully submitted that the data illustrates an unexpected synergistic effect obtained from the combination of the zinc PTO anti-dandruff agent and conjugated linoleic acid.

As noted by the Examiner, Hersh discloses antidandruff compositions that contain zinc-PTO. There is nothing in the citation that discloses or suggests the use of CLA in such compositions.

Hoppe et al. discloses the use of **bioquinones** to prolong the analgenic phase of hair growth and to treat dandruff. There is nothing in the citation that discloses or suggests that **CLA** (described therein as improving the energy metabolism in the hair root) would be effective in treating **scalp itch**. In fact, the Group 1 data provided in the subject application suggests that CLA can actually increase scalp itch. Moreover, there is nothing in Hoppe et al. that suggest the equivalence of zinc PTO for bioquinones in the compositions therein described. Additionally, there is nothing in Hoppe et al. or Herb, individually or in combination, that would that disclose or suggest that the combination of CLA, a an ingredient that can increase scalp itch, used in conjunction with an antidandruff agent like zinc PTO, would operate to reduce scalp itch.

It is respectfully suggested that the Applicants have demonstrated an unexpected and synergistic reduction in scalp itch provided by the subject compositions that would not be suggested or predicted from the applied citations.

For the reasons set forth above it is respectfully submitted that the subject claims are not rendered obvious by the combination of Hoppe et al. and Hersh. Accordingly, reconsideration and allowance of the claims as hereby amended is respectfully requested.

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If a telephone conversation would be of assistance in advancing the prosecution of the present application, applicants' undersigned attorney invites the Examiner to telephone at the number provided.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Karen E. Klumas", written over a horizontal line.

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